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Mr. Chairman, distinguished members of the Committee and staff – good afternoon. Thank you for convening this hearing on policy issues surrounding the data collection and reporting of hospital-acquired infections ("HAIs").

My name is Dr. Scott Hammer, and I am the Chief of the Adult Division of Infectious Diseases and a Professor of Medicine and Epidemiology at the NewYork-Presbyterian Hospital/Columbia University Medical Center ("NYPH"). NYPH is the largest single hospital and academic medical center in the New York metropolitan area, and is affiliated with two medical schools: the Columbia University College of Physicians & Surgeons; and Cornell University's Weill Medical College. Collectively, our five separate campuses serve a vast geographic region and a diversity of communities. On behalf of NYPH, I appreciate the opportunity to testify this afternoon and share my insights on the benefits and challenges presented by legislative measures requiring hospitals to collect, monitor and report HAI data.

I. OVERVIEW

At the outset, I would like to acknowledge the importance of the Committee's inquiry into HAIs – an issue that poses significant challenges to the public health system in the United States. In a February 2005 report, the Healthcare Infection Control Practices Advisory Committee ("HICPAC") estimated that each year, HAIs account for two million infections, and $4.5 billion in excess healthcare costs. As significant as these statistics may seem, they do not adequately convey the impact that HAIs can have on the lives of patients and their families.

Accordingly, NYP supports efforts to require the public reporting of HAI data, provided that it is collected and calculated properly, and conveyed to the public in a responsible, comprehensive, and meaningful manner. Thus, any approach mandating the disclosure of HAI rates should address two fundamental issues. First, the legislation should establish national standards regarding methodologies for: (i) the collection of HAI data; (ii) the calculation of HAI rates; and (iii) the presentation of HAI rates. Second, the reporting framework should establish an effective risk-adjustment procedure to correct for variances among patient populations with respect to underlying risk factors for infection.

In order to formulate an effective national reporting system, this process will require consultation among the various public and private stakeholders, including: (i) the Centers for Disease Control and Prevention ("CDC"); (ii) state health departments; (iii) hospitals and other health care facilities, including academic medical centers; (iv) national associations representing infection control practitioners, such as the Association for Professionals in Infection Control and Epidemiology ("APIC"), and the Society for Healthcare Epidemiology of America ("SHEA"); and (v) non-profit patient advocacy groups.

II. LACK OF CONSENSUS AMONG FEDERAL AND STATE REGULATORY FRAMEWORKS ON METHODOLOGIES FOR COLLECTING AND CALCULATING HAI DATA

Currently, multiple federal and state regulatory frameworks provide guidance for the collection and dissemination of HAI data. These approaches can conflict in significant respects, however, often directing facilities to adopt varying definitions and methodologies when collecting HAI data and calculating HAI rates. The present lack of methodological consensus among federal and state regulatory frameworks means that hospitals adopting different approaches will not be subject to valid comparisons, which ultimately is the primary goal of public reporting. Given the technology, effort and expense required to gather accurate HAI data, it is important to insure that hospitals be required to work within a single regulatory regime with respect to HAI reporting.

On the federal level, no law currently in effect requires public reporting of HAI data. On a voluntary basis, however, some hospitals presently report HAI data to the National Nosocomial Infections Surveillance Network ("NNIS"), sponsored by the CDC. NNIS requires participating hospitals to collect HAI data using standardized protocols called "surveillance components," which target the adult and pediatric intensive care, high-risk nursery, and surgical patient units. For a minimum period of one month, participating hospitals must track all incidences of HAIs within the surveillance components. They then categorize incidences of HAIs into major and specific infection sites, using definitions developed by the CDC.

The CDC/NNIS methodologies for collecting HAI data and calculating HAI rates have been influential and form the closest existing approximation to a national standard. But the CDC/NNIS standard has not achieved universal acceptance. Notably, the only federal legislation that would require hospitals to report HAI data appears in a provision of the Deficit Reduction Act ("DRA"). Enacted on February 8, 2006, but not yet in effect, the DRA adopts neither the CDC definitions for HAIs, nor the CDC/NNIS rate-calculation methodologies. Rather, the DRA directs

the Secretary of Health and Human Services (the "Secretary") to develop the agency's own definitions and methodologies for collecting HAI data and calculating HAI rates, in consultation with the CDC and other appropriate national consensus building entities. The Secretary also must select two HAIs for acute care hospitals to track through admission and discharge codes, and include pneumonia and surgical site infection data in its group of quality indicators. The DRA expands the number of quality indicators that acute care hospitals must monitor and report in exchange for receiving the maximum price inflation adjustment under the Medicare program. And, under the DRA, by October 1, 2008, Medicare would not provide a facility with full reimbursement of treatment expenses if patients develop either of these two selected HAIs.

On the state level, six legislatures have enacted laws mandating public reporting of HAIs.[1] Many of these have yet to become effective, with others merely in the early stages of implementation. Like the DRA, however, a number of these states have opted to direct the development of their own methodologies on collection of HAI data and calculation of HAI rates, rather than adopt the CDC or NNIS models. New York, for example, requires its Department of Health to create methodologies for infection identification, coding, tracking and reporting. The Pennsylvania law establishes similar requirements. On the other hand, Florida requires its hospitals to collect HAI data using the distinct methodologies developed by the Centers for Medicaid and Medicare Services ("CMS").

Given that federal and state regulatory frameworks employ disparate methodologies for collection of HAI data and for calculation of HAI rates, attempted comparisons among hospitals falling within different regulatory frameworks may yield results that are suspect and difficult to interpret. In order to be of value to the healthcare community and the public, any proposed

[1] Two additional states – Nevada and Nebraska – also have enacted legislation to require the collection and calculation of HAI rates, however, the resulting data are reported only to the state agencies responsible for public health, and presently are not disclosed to the public.

legislation mandating public reporting of HAI data must establish uniform methodologies for collecting HAI data and calculating HAI rates.

One proposed approach towards achieving this uniformity would be to require hospital participation in NNIS. NNIS then could make its HAI database available to state agencies, which could use the data to compare hospitals and identify potentially problematic trends. Where appropriate, such state agencies could take further action against specified hospitals.

Such mandatory hospital participation in NNIS would pose challenges for two reasons. First, the CDC is in the process of redesigning the NNIS system into a user-friendly web-based resource, called the National Healthcare Safety Network ("NHSN"). Although there has been no formal announcement of a precise launch date, the CDC projects that the NHSN will be operational at some point in 2006. Until that occurs, and understandably for some period of time afterwards, the system may undergo additional changes toward becoming an effective resource for the health care community.

Second, the NNIS (as well as the successor NHSN), is designed to report only outcome measures, which establish the rate of infection for certain diseases within targeted patient populations (*e.g.*, the number of patients who contract pneumonia from ventilators). Moreover, the NHSN changes the current list of NNIS outcome measure requirements by collecting data for a narrower range of HAIs – namely, central-line associated bloodstream infections, ventilator associated pneumonia, catheter-associated urinary tract infections, and surgical site infections.

Highlighting the lack of consensus with respect to HAI reporting, the NNIS approach does not provide for the collection or distribution of information regarding adherence to process measures, which determine the hospital staff's adherence to procedures believed to reduce the spread of HAIs (*e.g.*, the number of influenza vaccinations administered to staff). Notably, the HICPAC report concluded that outcome measures, like the ones required by NHSN and NNIS,

often are more difficult to observe accurately than process measures. In its view, process measures should form the core of a mandatory reporting system because: (i) they are easy to observe; (ii) hospitals should unambiguously aim for 100% adherence to measured processes; and (iii) they do not have to be adjusted for a patient's underlying risk of infection. Consequently, HICPAC believes that outcome measures are more costly to implement, but ultimately produce a less reliable indication for the performance of HAI control programs.

III. LACK OF CONSENSUS AMONG HOSPITALS ON METHODOLOGIES FOR COLLECTING AND CALCULATING HAI DATA

Hospitals have long employed differing methodologies for collecting HAI data and calculating HAI rates. For instance, a given facility may track process measures, outcome measures, or a combination of both as indices of their own internal HAI-related performance. Accordingly, it would not be meaningful to attempt a comparison between the HAI rates of a hospital using primarily process measures with one primarily observing outcome measures.

Even when opting to gather similar types of data (i.e., process measures vs. outcome measures), hospitals can monitor different processes and outcomes. For example, NYPH calculates HAI rates through outcome measures by conducting targeted surveillance of specific types of infections, including: (1) central venous catheter bloodstream infections in the Intensive Care Unit ("ICU"); (2) surgical site infections in select patient populations; (3) epidemiologically-significant resistant organisms, such as Methicillin-resistant Staphylococcus Aureus ("MRSA") and Vancomycin-resistant Enterococcus ("VRE"); (4) Rotavirus infections; and (5) Respiratory Syncytial Virus ("RSV") infections. NYPH also monitors certain process measures associated with HAIs, such as hand hygiene (through a direct observation program), and influenza vaccination rates (based on the number of staff members who receive an immunization).

On the other hand, our peer hospitals that also monitor process measures may reasonably have selected alternative procedures to target. Similarly, when tracking outcome measures, other facilities may collect data on different infectious agents. Each of these approaches may be equally valid, yet entirely distinct. Thus, any comparison among hospitals using disparate process or outcome measures would – at best – not be informative. At worst, any attempt to produce a comparison among these statistics invariably could prove misleading and potentially harmful to our nation's healthcare consumers.

IV. THE IMPORTANCE OF STANDARDIZING RISK-ADJUSTMENT PROCEDURES

From one facility to the next, healthcare facilities treat an array of patient populations, reflecting various levels of acuity. By virtue of our geographical location and affiliation with Columbia University Medical Center and Weill Cornell Medical Center, NYPH serves a wide range of communities, including some of the nation's most vulnerable, living within economically-disadvantaged neighborhoods such as Harlem and Washington Heights. Moreover, as an academic medical facility, NYPH often performs extremely specialized and high-risk procedures for patients with diseases that community hospitals lack the expertise or resources to treat. For instance, NYPH serves as the burn center for the New York City Fire Department, and cares for numerous patients who have received an organ transplant. Each of these patient groups is inherently vulnerable to the threat of elevated HAI rates due to the use of immunosuppressant medications, which would require significant risk adjustment prior to being reported in comparison to other patient groups and other facilities.

Furthermore, without effective risk adjustment to correct for these disparate patient populations and acuity levels, it would be very challenging to generate a meaningful comparison between HAI rates at academic medical centers (and other tertiary hospitals), with the rates observed at a typical community medical center. Moreover, in some situations it has become

increasingly difficult to identify whether an infection was acquired while at the hospital, or within the community (*e.g.*, the current epidemic of community-associated MRSA infections). Risk-adjustment of outcome measures therefore is critical, because it enforces the validity of inter-hospital comparisons and addresses the issue of whether an infection likely was acquired during or prior to a patient's hospital stay.

Unfortunately, the risk adjustment methods currently available are limited in their ability to account for differences in patient population and acuity levels among facilities. As noted in the HICPAC report, "current risk adjustment techniques improve but do not guarantee the validity of inter-hospital comparisons, especially comparisons involving facilities with diverse patient populations *(i.e.*, community versus tertiary-care hospitals)." Current risk adjustment procedures thus incorporate only a portion of all potential confounding variables, and as such they are limited in their ability to correct for variability among data collectors in the accuracy of locating and reporting events.

Unadjusted or poorly-adjusted HAI rates may lead to unintended and undesirable consequences. For example, a patient misinterpreting HAI data may avoid seeking treatment at a particular facility, despite its being more experienced and better-equipped to treat the patient's condition. And as noted above, with reimbursement rates increasingly becoming tied to outcomes, the public reporting of HAI rates may lead to decreasing reimbursements from third-party payors and a loss of patient revenues at facilities with higher infection rates.

Given this lack of uniformity in the current HAI methodologies for collecting data, calculating rates, and adjusting for risk, facilities that publicly report also may face undue negative publicity and misplaced legal liability, each of which would undermine efforts to serve patients and their communities. In the absence of a consensus for definition, measurement, data capture and

denominator consistency, the release of current data may misrepresent the HAI environment to the public.

In order for the public reporting of HAI rates to achieve the Committee's objective – to provide patients and their families with educated decision making tools – such rates should ensure adjustments for acuity level, patient mix, and other considerations. Moreover, the federal and state reporting agencies should remind consumers that HAI rates are not to be viewed in isolation. Consumer interest groups and professional associations also play a role in the process to educate patients and their families about the benefits and limitations of HAI data. In the end, the public should understand that HAI rates represent only one of a myriad of factors to be used in deciding where to receive quality healthcare.

Thank you, Mr. Chairman, and I would be pleased to answer any of your questions.